



PTO/SB/08A (10-01)

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Substitute for form 1449A/PTO

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(use as many sheets as necessary)

Sheet	1	of	3	Attorney Docket Number	13024/38629A
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U. S. PATENT DOCUMENTS

Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document
		Number-Kind Code ² (if known)		
✓	A1	5,240,846	08-31-1993	Collins et al.
✓	A2	5,292,498	03-08-1994	Boucher, Jr.
✓	A3	5,420,116	05-30-1995	Puchelle et al.
✓	A4	5,470,838	11-28-1995	von Borstel et al.
✓	A5	5,576,289	11-19-1996	McMichael, J.
✓	A6	5,726,160	03-10-1998	McMichael, J.
✓	A7	5,736,508	04-07-1998	McMichael, J.
✓	A8	5,948,768	09-07-1999	McMichael, J. et al.
✓	A9	5,955,442	09-21-1999	McMichael, J.

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Country
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)		
✓	B1	WO 92/11016	07/09/92	WIPO
✓	B2	WO 93/12240	06/24/93	WIPO
✓	B3	WO 94/23048	10/13/94	WIPO
✓	B4	WO 95/25800	09/28/95	WIPO
✓	B5	WO 96/32138	10/17/96	WIPO
✓	B6	WO 96/40059	12/19/96	WIPO
✓	B7	WO 97/05195	02/13/97	WIPO

OTHER PRIOR ART - NON PATENT LITERATURE DOCUMENTS

Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓	C1	Alton, E.W.F.W. et al., "Noninvasive liposome-mediated gene delivery can correct the ion transport defect in cystic fibrosis mutant mice," <i>Chemical Abstracts</i> , 119:62 (1993) (ABSTRACT 217089w)	
✓	C2	Badesch et al., "Continuous Intravenous Epoprostenol for Pulmonary Hypertension Due to the Scleroderma Spectrum of Disease. A Randomized, Controlled Trial," <i>Ann. Intern. Med.</i> , 132:425-434 (2000).	
✓	C3	Baker, R.C., "Pitfalls in Diagnosing Acute Otitis Media," <i>Pediatric Annals</i> , 20:591-593; 596-598 (1991).	
✓	C4	Barst et al., "A Comparison of Continuous Intravenous Epoprostenol (Prostacyclin) With Conventional Therapy for Primary Pulmonary Hypertension," <i>N. Eng. J. Med.</i> , 334:296-301 (1996).	

Examiner Signature	<i>Valerie Liles</i>	Date Considered	09/14/06
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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Substitute for form 1449B/PTO			<i>Complete if Known</i>	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>			Application Number	10/764,161
			Filing Date	January 23, 2004
			First Named Inventor	John McMichael
			Group Art Unit	1054 1655
			Examiner Name	To be assigned <i>Ronald W. Johnson</i>
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✓	C5	Berkow, R. (Ed.), <i>The Merck Manual of Diagnosis and Therapy</i> , Sixteenth Edition, Merck Research Laboratories, Division of Merck & Co., Inc., Rahway, N.J. pp. 600-602 (1992).
✓	C6	Berman, S., "Otitis Media in Developing Countries," <i>Pediatrics</i> , 96:126-131(1995).
✓	C7	Canonico, A.E. et al., "Expression Of A Cmv Promoter Driven Human A-1 Antitrypsin Gene In Cultured Lung Endothelial Cells And In The Lungs Of Rabbits," <i>Clin. Res.</i> , 39(2): 219A (1991).
✓	C8	Carman et al., "A Primary Care Approach to the Patient with Claudication," <i>Am. Fam. Physician</i> , 61:1027-1032 (2000).
✓	C9	Cunningham, M.W., "Pathogenesis of Group A Streptococcal Infections," <i>Clin. Microbiol.</i> 13:470-511 (2000).
✓	C10	Dagan, R. et al., "Treatment Failures in Otitis Media-What Can We Learn?," <i>Ear, Nose and Throat J.</i> , 77:16-21(1998).
✓	C11	Dawson et al., "Cilostazol Has Beneficial Effects In Treatment of Intermittent Claudication," <i>Circulation</i> , 98:678-686 (1998).
✓	C12	DeGraves et al., "Economics of Mastitis and Mastitis Control," <i>The Veterinary Clinics of North America-Food Animal Practice Update on Bovine Mastitis</i> , 9:421-434 (1993).
✓	C13	Flotte, T.R., et al., "Stable <i>in vivo</i> expression of the cystic fibrosis transmembrane conductance regulator with an adeno-associated virus vector," <i>Chemical Abstracts</i> , 120:229(1994) (ABSTRACT 46918e)
✓	C14	Furth et al., "Gene Transfer into Somatic Tissues by Jet Injection," <i>Analytical Biochemistry</i> , 205:365-368 (1992).
✓	C15	Gent et al., "A Randomised, Blinded, Trial of Clopidogrel Versus Aspirin in Patients at Risk of Ischaemic Events (CAPRIE)," <i>Lancet</i> , 348:1329-1339 (1996).
✓	C16	Gardner et al., "Exercise Rehabilitation Programs for the Treatment of Claudication Pain: A Meta Analysis," <i>JAMA</i> , 274:975-980 (1995).
✓	C17	Goldhaber et al., "Low-Dose and Subsequent Peripheral Arterial Surgery in the Physicians' Health Study," <i>Lancet</i> , 340:143-145 (1992).
✓	C18	Harrison et al., "Structural Features of Interstitial Lung Disease in Systemic Sclerosis," <i>Am. Rev. Respir. Dis.</i> , 144:706-713 (1991).
✓	C19	Hood et al., "Management of Intermittent Claudication with Pentoxyfylline: Meta-Analysis of Randomized Controlled Trials," <i>CMAJ</i> , 155:1053-1059 (1996).
✓	C20	Janzon et al., "Prevention of Myocardial Infarction and Stroke in Patients with Intermittent Claudication; Effects of Ticlopidine. Results from STMS, the Swedish Ticlopidine Multicentre Study," <i>J. Intern. Med.</i> , 27:301-308 (1990).
✓	C21	Jarrow et al., "Peyronie's Disease and Radical Prostatectomy: Is There A Link?," <i>J. of Urology</i> , 158:1388-1390 (1997).
✓	C22	Karver, S.B., "Otitis Media," <i>Ear, Nose and Throat Disorders</i> , 25:619-632(1998).
✓	C23	Klein, J.O., "Otitis Media," <i>Clinical Infectious Disease</i> , 19:823-833 (1994).
✓	C24	Ledley, F.D., "Non-viral gene therapy," <i>Current Opinion in Biotechnology</i> , 5: 626-636 (1994).
✓	C25	Ledley, F.D., "Nonviral Gene Therapy: The Promise of Genes as Pharmaceutical Products," <i>Human Gene Therapy</i> , 6: 1129-1144 (September, 1995).
✓	C26	Marshall, E., "Gene Therapy's Growing Pains," <i>Science</i> , 269: 1050-1055 (1995).

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				First Named Inventor	John McMichael
				Group Art Unit	1654 1655
				Examiner Name	To be assigned <i>ANDAI / WARD</i>
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<i>w</i>	C27	Patterson et al., "Value of a Supervised Exercise Program for the Therapy of Arterial Claudication," <i>J. Vasc. Surg.</i> , 25:312-319 (1997).	
<i>w</i>	C28	Razin et al., "Protein Kinases C- β and C- ϵ Link the Mast Cell High-Affinity Receptor for IgE to the Expression of c-fos and c-jun," <i>Proc. Natl. Acad. Sci. (USA)</i> , 91:7722-7726 (1994).	
<i>w</i>	C29	Rosenfeld, M.A. et al., "Adenovirus-Mediated Transfer of a Recombinant α 1-Antitrypsin Gene to the Lung Epithelium in Vivo," <i>Science</i> , 252: 431-434(1991).	
<i>w</i>	C30	Rosenfeld, J. et al., "Acute Otitis Media in Children," <i>Primary Care; Clinics in Office Practice</i> , 23(4):677-686(1996).	
<i>w</i>	C31	Ruiz et al., "Streptolysin O and Adherence Synergistically Modulate Proinflammatory Responses of Keratinocytes to Group A Streptococci," <i>Mol. Microbiol.</i> 27:337-346 (1997).	
<i>w</i>	C32	Schrager et al., "Hyaluronic Acid Capsule Modulates M Protein-Mediated Adherence and Acts as a Ligand for Attachment of Group A <i>Streptococcus</i> to CD44 on Human Keratinocytes," <i>J. Clin. Investig.</i> 101:1708-1716 (1998)	
<i>w</i>	C33	Silver et al., "Evaluation and Management of Scleroderma Lung Disease Using Bronchoalveolar Lavage," <i>Am. J. Med.</i> , 88:470-476 (1990).	
<i>w</i>	C34	Unemori et al., "Relaxin Modulates Synthesis and Secretion of Procollagenase and Collagen by Human Dermal Fibroblasts," <i>J. Biol. Chem.</i> , 265:10681-10685 (1990).	
<i>w</i>	C35	Visa et al., "The Value of Fasciectomy in the Surgical Approach of the Dupuytren's Disease," <i>Romanian Journal of Hand and Reconstructive Microsurgery</i> , 5:9-13 (2000).	
<i>w</i>	C36	Wallaert et al., "Subclinical Pulmonary Involvement in Collagen-Vascular Diseases Assessed by Bronchialveolar Lavage," <i>Am. Rev. Respir. Dis.</i> , 133:574-580 (1986).	
<i>w</i>	C37	White et al., "Cyclophosphamide is Associated with Pulmonary Function and Survival Benefit in Patients with Scleroderma and Alveolitis," <i>Ann. Intern. Med.</i> , 132:947-954 (2000).	
<i>w</i>	C38	Siebold et al., "Recombinant Human Relaxin in the Treatment of Scleroderma, A Randomized, Double-Blind, Placebo-Controlled Trial," <i>Ann. Intern. Med.</i> , 132:871-879 (2000).	
<i>w</i>	C39	Murinda et al., "Isolation of Mastitis and Food-Borne Pathogens in Bulk Tank Milk and Fecal Samples from Cull Dairy Cows," Schrick et al., <u>Department of Animal Science Annual Report</u> , The University of Tennessee, Knoxville, in press.	
<i>w</i>	C40	Taranta et al., "The Relationship of Sydenham's Chorea to Infection with Group A Stretococci," <i>Am. J. Med.</i> , 20:170-175 (1956).	
<i>w</i>	C41	Kiessling et al., "Antineuronal Antibodies in Movement Disorders," <i>Pediatrics</i> , 92:39-43 (1993).	
<i>w</i>	C42	Askanas et al., "A New Program for Investigating Adult Human Skeletal Muscle Grown Aneurally in Tissue Culture," <i>Neurology</i> , 25:58-67 (1975).	

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		Number-Kind Code ² (if known)			
✓ A	US-6,096,721	08-01-2000	McMichael		
✓ B	US-6,303,127	10-16-2001	McMichael et al.		
✓ C	US-6,447,820	09-10-2002	Niazi		

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Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ³
		Country Code ⁴ -Number ⁴ -Kind Code ⁵ (if known)				

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NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
✓ D		International Search Report corresponding to International Patent Application Serial No. PCT/US04/01887 dated August 26, 2004, 2 pages.	

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